The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

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Gray Matters

As the saying goes, “life comes at you fast.” Nothing has highlighted that more in the past couple of years than artificial intelligence (AI). CDER Director Patrizia Cavazzoni has said, “AI and machine learning (ML) are no longer futuristic concepts; they are now part of how we live and work. FDA uses the term AI to describe a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions. ML is a subset of AI that uses data and algorithms, without being explicitly programmed, to imitate how humans learn.” FDA last year released two discussion papers on AI and ML. You can access the first paper here. You can access the second paper here. I think these papers are a great way to dip a toe into what FDA is already doing on AI and the challenges we face – I recommend you give them a read.

OPDP’s parent office, the Office of Medical Policy, is leading a cross-center initiative to establish policies that harness the potential and advance the quality of AI use in

drug development. Just last month, OMP's efforts significantly contributed to publication of a paper titled "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together" which provides greater transparency regarding how we are collaborating to align efforts that advance the responsible use of AI for medical products. This entails building regulatory approaches that, to the extent feasible, can be applied across various medical products and uses within the health care delivery system. There's also a new landing page for Artificial Intelligence and Medical Products to simplify finding these papers and other resources.

This newsletter is a mechanism for me to catch up with you all. Speaking of catching up, I promised that we would cover all things digital, and this issue we have some great features expanding on our previous announcements about last year's Duke-Margolis public meeting on the Future of Prescription Drug Promotion and Digital Marketing, a roundtable discussion on Responsive Search Ads (RSA), and hot off the presses content about a session at DIA Ad/promo on Omnichannel marketing. We also have a deep-dive analysis of the 5-day screening period for launch submissions submitted since January 2021.

Read on for more!

Best,

kbg

On January 18, 2024, OPDP issued an Untitled Letter (UL) to Novartis Pharmaceuticals Corporation regarding the company's product Kisqali (ribociclib) tablets. The UL is posted on the OPDP Untitled Letters webpage.

The Social Science team published two new manuscripts:

Physician interpretation of information about prescription drugs in scientific publications vs. promotional pieces[1]

Disease Awareness and Prescription Drug Communications on Television: Evidence for Conflation and Misleading Product Impressions[2]

[1] Aikin, K. J., O'Donoghue, A. C., Miles, S., DelGreco, M., & Burke, P. (2024). Physician interpretation of information about prescription drugs in scientific publications vs. promotional pieces. Research in social & administrative pharmacy : RSAP, 20(4), 419–431. https://doi.org/10.1016/j.sapharm.2024.01.003

[2] Betts, K. R., Aikin, K. J., Miles, S., & Eisenberg Colman, M. H. (2024). Disease Awareness and Prescription Drug Communications on Television: Evidence for Conflation and Misleading Product Impressions. Health communication, 1–11. Advance online publication. https://doi.org/10.1080/10410236.2024.2323839

Special Focus: All Things Digital

Duke-Margolis Public Meeting – The Future of Prescription Drug Promotion and Digital Marketing

In September 2023, the Duke-Margolis Institute for Health Policy, under a cooperative agreement with FDA, hosted a one-day public meeting titled "The Future of Prescription Drug Promotion and Digital Marketing." A joint panel representing both Duke-Margolis and OPDP presented the keynote address at the March 2024 DIA Advertising and Promotion Regulatory Affairs conference and announced the publication of the meeting final report.

The Duke-Margolis public meeting gathered a wide array of experts in marketing, media, industry, and prescription drug promotion along with patient advocates, consumers, and healthcare providers. The meeting sought to explore the development and introduction of new platforms and digital formats in prescription drug promotion and how patients, consumers, and healthcare providers alike interact, perceive, and understand emerging digital promotion.

The meeting hosted four panels, each focused on specific topics that are especially relevant to new and emerging digital marketing channels. The first panel discussed the future of television. Panelists discussed the current state of linear and streaming

television and the trends and emerging technologies that will shape television promotion in the coming years. The second panel covered the increasing use of influencers and native advertising in the prescription drug space. New digital formats, including both long and short-form video, have introduced consumers and healthcare providers alike to new targeted forms of advertising that may not always be clearly identifiable as promotional messaging. Panel three hosted a varied collection of patient advocate groups and consumers who spoke about the emerging trends and challenges related to consumer-directed digital advertising. Finally, the meeting concluded with a panel discussion of emerging trends and platforms targeting healthcare providers in the digital space.

Overall, the meeting was a success and panelists shared many invaluable insights into both the current state of prescription drug digital marketing and the emerging trends and technologies that we will see in the years ahead. Be on the lookout for the next Duke-Margolis public meeting on digital marketing in 2024.

Responsive Search Ads

In October 2023, DIA hosted a roundtable discussion on Responsive Search Ads (RSA). Since 2022, RSA has been the predominant method for publishing sponsored ads on major search platforms. However, RSA presents many challenges to marketers in the prescription drug space. The roundtable presented an overview of RSA and how it functions before turning to a panel discussion of best practices for regulatory affairs/operations, ad agency, and PRC/MLR staff. The panel was moderated by Jason Cober, OPDP's Lead Project Manager, who also discussed submission requirements for Form FDA 2253 and how companies can submit not only RSA but other variable-type submissions to OPDP to maintain regulatory compliance. A recording of the discussion is free to access once you provide your contact information.

Variable Content, Modular Content, Multichannel, and Omnichannel Marketing

During the March DIA Ad/Promo conference, OPDP's Lead Project Manager, Jason Cober, participated in a panel discussion with consultant Zoe Dunn titled "Preparing Promotional Review for the Shift to Omnichannel Marketing." As marketers increasingly rely on automation to develop and post variable and modular marketing content, it's important to remember that these promotional communications must be submitted on Form FDA 2253. The panel discussion focused on the emerging use of multichannel and omnichannel marketing and how variable and modular content fits within those strategies. Jason also highlighted OPDP's efforts to foster improved communication with submitters and directed firms to the OPDP eCTD mailbox (OPDPeCTD@fda.hhs.gov) for questions or assistance with preparing regulatory submissions for variable or modular content. Often the details of a given promotional campaign are important to understanding how firms will distribute variable and modular promotional communications, and a phone call with the OPDP Project Management team may be helpful to provide submission guidance. During the panel discussion,

Jason outlined how firms can prepare for a call with OPDP regarding variable and modular content and noted that the OPDP team would provide any specific questions they have for firms in advance of the meeting.

Deep Dive: Core Launch Screening Process

Core Launch Screening Process Evaluation

As of January 2021, upon receipt of a submission requesting comments on proposed core launch materials, OPDP review and project management staff conduct a 5-business day administrative content review to determine if the submission is complete, annotated to clearly identify the source of support for each claim, and consistent with core launch parameters.

OPDP conducted an evaluation of all core launch submissions received from January 2021 until September 2023 and discovered the following:

- A majority of core launch submissions successfully pass the 5-business day screening process, with roughly 1 in 3 submissions failing to pass (32%).
- Of the core launch submissions that fail the screening process, 57% are not consistent with core launch parameters, 30% are not complete and acceptable for review, and 13% are both not consistent with core launch parameters and not complete and acceptable for review.
- When a submission is not consistent with core launch parameters, the most common reasons are:
    - The types of materials, number of materials, and/or page limitations for materials in the submission are not consistent with the core launch parameters.
    - The claims and presentations are not based solely on the information contained in the PI, the pivotal/registration trials, or publications directly related to those trials.
- When a submission is not complete and acceptable for review, the most common reasons are:
    - The claims and presentations in the pieces are not annotated when necessary.
    - The annotations do not correlate correctly to the references.

OPDP encourages firms to refer to the guidance titled, “Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs” (OPDP Electronic Submission

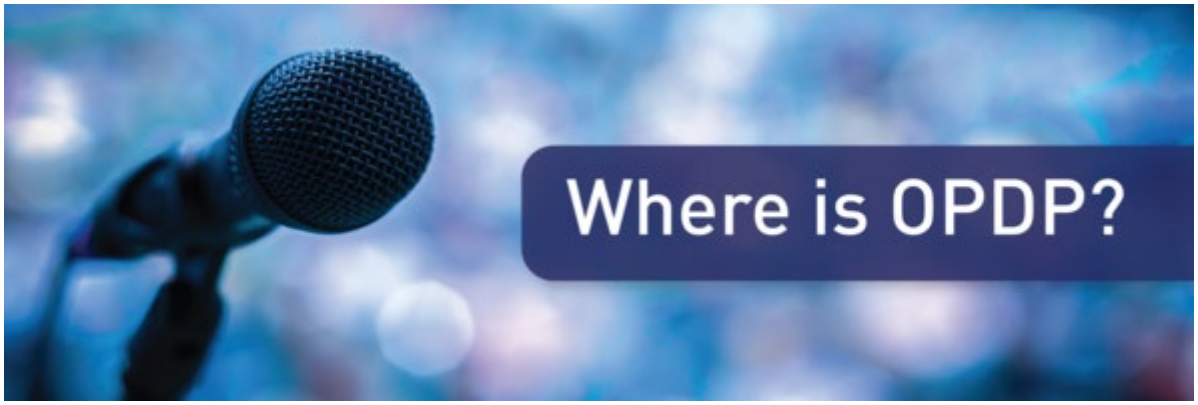
Guidance) for descriptions of the types of materials OPDP considers to be core launch (Section IV.C.1) and for information on how to annotate promotional materials, product labeling, and references (Section VI.F.3, VI.G.2, and VI.H, respectively). Additional information on launch submissions can be found on OPDP's FAQ webpage, including a mock annotated promotional piece as an example of how to appropriately annotate a promotional piece for OPDP review.

Staff Spotlight

Alpita Popat, Health Science Policy Analyst

I earned my PharmD and Master in Business Administration from Drake University in 2001. I then completed a post-doctoral fellowship in Medical Communications through Rutgers State University. Prior to joining FDA, I was a Pharmacy Manager at CVS, Medical Information Specialist and MSL at Abraxis BioSciences, Inc, and then an Account Supervisor at Abelson-Taylor.

I joined the Division of Promotion Policy, Research and Operations (DPPRO) in March 2021 as a Health Science Policy Analyst after working for 10 years as a regulatory reviewer for the Advertising Promotional and Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER). My expertise includes biological products and product labeling. I enjoy working in OPDP because it allows me to contribute to and shape how industry can promote their products in a truthful and non-misleading way to patients and healthcare providers.



OPDP Office Director Katie Gray, DPPRO Director Kathleen David, DPPRO Deputy Director Amy Muhlberg, and DPPRO Lead Project Manager Jason Cober presented at the DIA Advertising and Promotion Regulatory Affairs Conference on March 12-13, 2024.

The Office of Prescription Drug Promotion (OPDP) resides in the Office of Medical Policy (OMP) in the Center for Drug Evaluation and Research (CDER).

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